K092852

MAR 11 2010

VI. 510(k) Summary

In response to the requirements of the safe Medical Devices Act of 1990, a summary of the safety and effectiveness information upon which the substantial equivalence determination is based is included in this submission.

510(k) Summary

Submitter Information:

St. Shine Optical Co., Ltd.
4,5F No, 276-2, Sec. 1, Ta Tung Rd.
Hsi Chih City, 221 Taipei County
Taiwan R.O.C.
Registration No. 9617499

Contact Person: Brian Lai
Manager, Regulatory Affairs

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Date Prepared: September 15, 2009

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Name: Saview 58 UV (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Saview 58 UV Toric (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Saview 58 UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

ACUVUE (etafilcon A) Contact Lens clear and visibility tint with UV blocker, 55 UV (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear, 55 UV Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear and 55 UV Toric (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear are selected as the predicate devices.

The ACUVUE lenses were cleared under 510(k) K962804, and are manufactured by a molding process that uses the etafilcon A material. The dye tinting is different; the lenses are tinted with Reactive Blue #4, where the Saview 58 UV lenses are tinted with Pigment Blue 15.

The 55 UV, 55 UV Toric, 55 UV Multifocal Soft Contact Lenses are cleared under 510(k) K051095, and are selected as predicate devices because although they are molded from a different material, they are tinted with the same dye, using the same UV blocker and the same lens designs, and produced in the same facility, under the same quality system, using the same molding, in-monomer tinting, packaging and sterilization processes as the Saview 58 UV, Saview 58 UV Toric, Saview 58 UV Multifocal (etafilcon A) Soft (hydrophilic) Contact Lenses.

Description of Devices:

The Saview 58 UV, Saview 58 UV Toric and Saview 58 UV Multifocal (etafilcon A) Soft (hydrophilic) Contact Lenses are available as a spherical lens for single vision, astigmatic (toric) lens and aspherical multifocal lens respectively. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with 1,1,1-trimethylol propane trimethacrylate, initiated by Azobisisobutyronitrile. A UV absorbing compound 2-[3-(2*H*-Benzotriazol-2yl)-4-hydroxyphenyl]ethyl methacrylate is incorporated into the lens polymer. The Saview 58 UV, Saview 58 UV Toric and Saview 58 UV Multifocal (etafilcon A) Soft (hydrophilic) Contact Lenses with visible tint are tinted blue using Pigment Blue 15 to make the lens more visible for handling.

PARAMETER Submission number	Saview 58 UV, Saview 58 UV Toric and Saview 58 UV Multifocal (etafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear N/A	ACUVUE (etafilcon A) Contact Lens clear and visibility tint with UV blocker K962804	55 UV, 55 UV Toric, 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear K051095
Material	etafilcon A	etafilcon A	methafilcon A
Material Classification	Group 4	Group 4	Group 4
Indication for use	myopia, hyperopia, astigmatism, and presbyopia	myopia, hyperopia, astigmatism, and presbyopia	myopia, hyperopia, presbyopia and astigmatism
Water content	58%	58%	55%
Visible light transmittance	91.752%	88.592%	90.3%
UV transmittance @280-315 mm @316-380 mm	UVB 2.016% UVA 14.937%	UVB 0.831% UVA 11.894%	UVB 2.435% UVA 15.816%
Dk (35℃)	26.3×10^{-11}	28×10^{-11}	18.9×10^{-11}
Powers	+12.00 ~ -12.00D	+20.00 ~ -20.00D	+4.00 ~ -20.00D
Color	Blue visibility Pigment Blue 15	Blue visibility Reactive Blue #4	Blue visibility Pigment Blue 15
Refractive index	1.3992	1.3988	1.415
Method of manufacture	Moulded	Moulded	Moulded

Indication for Use:

The **Saview 58 UV (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-disease eyes that may exhibit refractive and/or corneal astigmatism up to 1.00 diopters that does not interfere with visual acuity. Saview 58 UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **Saview 58 UV Toric (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or non-aphakic persons with non-diseased eyes. Saview 58 UV Toric lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **Saview 58 UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or non-aphakic persons with non-disease eyes that may exhibit refractive and/or corneal astigmatism up to 1.00 diopters that does not interfere with visual acuity. Saview 58 UV Multifocal lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eye care practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the **Saview 58 UV, the Saview 58 UV Toric, and** the **Saview 58 UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear**, and to establish substantial equivalence to the predicate devices.

Results of Acute Systemic Injection, Ocular Irritation and In Vitro Cytoticity Tests show the lenses to be non-toxic and non-irritating. The Saview 58 UV lenses were extracted and evaluated for presence of residue. Results showed no evidence of unsafe amounts of residue in the extracts. Physicochemical testing of the Saview 58 UV lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the Saview 58 UV, Saview 58 UV Toric and Saview 58 UV Multifocal Contact Lenses (etafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 11 2010

St. Shine Optical Co., Ltd.
c/o Mr. Brian Lai
Manager, Regulatory Affairs
4,5F No, 276-2, Sec. 1, Ta Tung Rd.
Hsi Chih City, 221 Taipei County
Taiwan R.O.C.

Re: K092852
Trade/Device Name: Saview 58UV (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Saview 58UV Toric (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Saview 58UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 6, 2010
Received: February 12, 2010

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

Device Names:

Saview 58 UV (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Saview 58 UV Toric (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Saview 58 UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

The **Saview 58 UV (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-disease eyes that may exhibit refractive and/or corneal astigmatism up to 1.00 diopters that does not interfere with visual acuity. Saview 58 UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **Saview 58 UV Toric (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or non-aphakic persons with non-diseased eyes. Saview 58 UV Toric lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The **Saview 58 UV Multifocal (etafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or non-aphakic persons with non-disease eyes that may exhibit refractive and/or corneal astigmatism up to 1.00 diopters that does not interfere with visual acuity. Saview 58 UV Multifocal lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eye care practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

Prescription Use ____X____ OR Over-the-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Mridula Virmani

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092852